



UNITED STATES DEPARTMENT OF COMMERCE  
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VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/114,265	07/13/98	TSUCHIYA	M

HM12/1013

FOLEY AND LARDNER  
3000 K STREET, N.W., SUITE 500  
PO BOX 18218  
WASHINGTON DC 20007-5109

EXAMINER  
BANSAL, G

ART UNIT  
127

PAPER NUMBER  
S  
10/13/99

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No. 09/114285 Applicant(s) Tsuchiya et al  
Examiner Goetha Bansal Group Art Unit 1642

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- Responsive to communication(s) filed on \_\_\_\_\_.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- Claim(s) 69-76 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 69-76 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). 1 Sheet  Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892  Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948  Other \_\_\_\_\_

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## **DETAILED ACTION**

1. Applicant's amendment filed 7/13/98 is acknowledged. Accordingly, claims 1-68 are canceled without prejudice, and claims 69- 76 are added. The Sequence Listing has been entered. The proposed drawing changes have ben entered.

Claims 69-76 are being examined.

2. Application must indicate the SEQ ID Nos in the Figures and wherever the sequences appear in the specification as per the requirements under 37 C.F.R. 1.821(d) (see M.P.E.P. 2422).

3. The drawings have been approved by the Office.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 69-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirata et al (1989) or Kishimoto (1991) in view of Oi et al (1986) or Morrison (1989).

The claims are drawn to a chimeric antibody to the human IL-6R comprised of murine variable regions and human constant regions.

Hirata et al teach monoclonal and polyclonal antibodies to human IL-6R, and the function of these antibodies in modulating the effect of IL-6R. Hirata et al teach hybridomas generating antibodies to the human IL-6R including the antibody PM-1 that was disclosed in the instant

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specification. Kishimoto teaches monoclonal antibodies to the human IL-6R and hybridoma producing such antibodies , and also discuss the potential development of therapeutic and diagnostic reagents (see page 6 column 1, lines 1-14). Hirata et al and Kishimoto do not teach a chimeric anti-IL-6R antibody. Oi et al and Morrison teach methods to make chimeric antibody molecules using murine variable regions and human constant regions and also teaches the potential clinical significance of making human - murine chimeric antibodies (see specially page 78 of Morrison; pg 216, column 1 top section of Oi et al). Therefore it would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the claimed invention to make chimeric antibodies to the human IL-6R by changing the murine antibodies taught by Hirata et all or Kishimoto using the methods taught by Oi et al or Morrison. One of ordinary skill in the art would be motivated to do so based on the fact that murine antibodies are immunogenic in humans and that using an antibody that more closely resembles the human antibody structure would be less immunogenic for human use as taught by Oi et al or Morrison. Though the exact sequences as claimed by the Applicant is not disclosed in the references above, it would be obvious to obtain DNA from the hybridoma cell lines taught by Hirata et al or Kishimoto, and identify and clone the V regions and recombinantly join them to human constant regions as taught by the Oi et al and Morrison references. The art was well known at the time of the claimed invention to have teaching related to identification of several human and mouse antibody genes and identification of the various regions, as well as recombinant gene technology. There is no disclosure in the specification that the specific sequences claimed are uniquely different as to make the claims unobvious over the cited prior art teachings.

5. No claim is allowable.

6. Papers related to this application may be submitted to Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal

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Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CMI Fax Center telephone number is (703) 308-4242 or (703) 305-3014.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Geetha P. Bansal whose telephone number is (703) 305-3955. The examiner can normally be reached on Mondays to Thursdays from 7:00am to 4:30pm and alternate Fridays from 7:00am to 3:30pm. A message may be left on the examiner's voice mail service.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Paula Hutzell, can be reached on (703) 308-4310.

8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

September 24, 1999.

GEETHA BANSAL  
PATENT EXAMINER  
